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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
11/29/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	08/619,649	DRMANAC, RADOJE	
	Examiner	Art Unit	
	Betty Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *97,157-182,185,186 and 188* is/are pending in the application.

5a) Of the above claim(s) *176* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *97,157-175,177-182,185,186 and 188* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12, 8/12*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

FINAL ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 May 2012 has been entered.

Status of the Claims

2. This action is in response to papers filed 25 May 2012 in which the previous rejections were traversed.

Applicant's arguments have been thoroughly reviewed and are discussed below.

The rejections in the Office Action dated 26 January 2012 are maintained.

Claims 97, 157-175, 177-182, 185-186, 188 are under prosecution.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

> applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 166, 169-170, 174-175, 179-180, 185 and 188 are rejected under 35 U.S.C. 102(e) as being anticipated by Chetverin et al (U.S. Patent No. 6,103,463, filed 19 February 1992) and/or under 35 U.S.C. 102(a) (WO 93/17126, published 2 September 1993).

The US patent and PCT publication contain identical subject matter. The teachings discussed below cite passages from the '463 patent. However, both references are considered prior art for the instant claims.

Regarding Claims 166, 179-180, Chetverin teaches a solid support (31) comprising an array of arrays (31a), wherein the arrays are separated by physical barriers to permit parallel execution of reactions and/or probe transfer in the arrays (Column 4, lines 6-30 and Column 10, lines 6-67) and wherein each array has different oligonucleotides (replica arrays, Column 11, lines 11-22 and/or miniature survey arrays, Column 30, lines 38-46 and Column 33, lines 15-27 and Fig. 7).

Regarding Claim 169, Chetverin teaches the oligonucleotides are arranged in rows and columns (Fig. 7B).

Regarding Claim 170, Chetverin teaches the arrays are arranged for adding reagents can be added or withdrawn from each array (Column 10, lines 6-67). While the reference does not specifically teach a pipette, the intended use as recited in the claim does not further define the structure of the device.

The courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claim 174, Chetverin teaches the oligos are 8-mers (paragraph spanning columns 32-33).

Regarding Claim 175, Chetverin teaches the arrays are prepared via photolithography (paragraph spanning columns 13-14).

Regarding Claims 185 and 188, Chetverin teaches an apparatus comprising a solid support (31) comprising a plurality of sections (31a), each comprising an array of oligonucleotides (miniature survey arrays,42) wherein the arrays are separated by physical barriers to permit parallel execution of reactions and/or probe transfer in the arrays (Column 4, lines 6-30 and Column 10, lines 6-67) wherein the arrays are different (Column 30, lines 38-46 and Column 33, lines 15-27 and Fig. 7).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 97, 159-160, 163-166, 169-171, 173-175, 177-182, 185-186 and 188 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) and Chetverin et al (U.S. Patent No. 6,103,463, filed 19 February 1992).

Regarding Claims, 97, 166, 177-182, 185, 186 and 188, Southern discloses a support comprising an array of four microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1). Southern teaches each array is in one of four quadrants on the surface (Fig. 3). The four-quadrant arrangement is encompassed by the physical separation because a quadrant defines a physical location of the surface. Assignment of an array to a quadrant defines a boundary between quadrants, the boundary being the point of physical separation.

Southern further teaches the support has duplicate arrays thereby providing arrays that are identical to other arrays, but different from others (Fig. 4 and accompanying text).

The reference specifically teaches that the arrays are physically separated i.e. "[T]o quantify the intensity in each cell, a grid was superimposed over the array so that each spot lay at approximately the center of the grid" (emphasis added: lines 8-9 of figure legend for Fig. 3). Thus, the reference specifically teaches a grid delineating the arrays but does not specifically teach the grid provides a physical barrier for keeping the arrays and/or probes in corresponding arrays.

Chetverin teaches similar solid support (31) comprising an array of arrays (31a), wherein the arrays are separated by physical barriers to permit parallel execution of

reactions and/or probe transfer in the arrays (Column 4, lines 6-30 and Column 10, lines 6-67) and wherein each array has different oligonucleotides (miniature survey arrays,42) (Column 30, lines 38-46 and Column 33, lines 15-27 and Fig. 7). Chetverin further teaches the advantages of sectioned array format (Column 4, lines 4-20):

A sectioned array allows many reactions to be performed simultaneously, both on the surface of the solid support and in solution, without mixing the products of different reactions. The reactions occurring in different wells are highly specific, the specificity of the reaction occurring in each well and is determined by the nucleotide sequence of the oligonucleotide immobilized on the surface. This allows a large number of sortings and manipulations of nucleic acids to be carried out in parallel, by amplifying or modifying only those nucleic acids in each well that are perfectly hybridized to the immobilized oligonucleotides.

Chetverin teaches the arrays are printed using well-known techniques (Columns 12-14) but does not teach microchips, more than 256 oligonucleotides or identical arrays. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the supports of Chetverin by providing the features as of Southern who teaches that the arrays provide a "powerful way of comparing related sequences and detecting mutations… to focus analysis on sequences of biological interest" (Abstract). The ordinary artisan would have been motivated to provide the arrays of Chetverin on microchips having more than 256 oligonucleotides and/or identical arrays. The artisan would have been motivated to do so for the advantages as taught by Southern (Abstract).

Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation for parallel reactions and/or reagent deposition to individual arrays as taught by Chetverin to the multiple arrays of Southern. Because Southern is specifically interested a grid for the array and individual array analysis (see above), the artisan would have been motivated to combine the teaching of Chetverin with that of Southern with a reasonable expectation of success and for the expected benefit obtaining a plurality of highly specific and independent reactions as taught by Chetverin (see above).

Regarding Claims 159 and 169, Southern discloses the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3). Chetverin also teaches the oligonucleotides are arranged in rows and columns (Fig. 7B).

Regarding Claims 160 and 170, Southern discloses the support wherein the microchips are positioned for use with a multichannel pipette (Fig. 3). The arrays of Southern are arranged in two rows of two columns. Chetverin also teaches the arrays are arranged for adding reagents can be added or withdrawn from each array (Column 10, lines 6-67).

While the references do not teach use of a multichannel pipette, as noted above, the courts have stated that device must be defined in terms of structure. The references teach the required structures as discussed above.

Regarding Claim 161 and 171, Chetverin teaches the array is used with labeled reagents and wash buffer (e.g. Column 6). It would have been obvious to one of

ordinary skill in the art at the time the claimed invention was made to combine the reagents used with the apparatus into a kit format for the well-known benefits of kit convenience.

Regarding Claims 163 and 173, Southern discloses the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claims 164 and 174, Southern discloses the support wherein the probes are between 4 and 9 bases (Fig. 3). Chetverin teaches the oligos are 8-mers (paragraph spanning columns 32-33).

Regarding Claims 165 and 175, Southern discloses the support wherein the probes are synthesized on the support (page 1009, left column). Southern does not teach light-directed synthesis. However, Chetverin teaches the arrays are prepared via photolithography (paragraph spanning columns 13-14).

Furthermore, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113.

Because determination of patentability is based on the product and because Southern teaches the product, the process of making the product as recited in the claim does not define the product over that of Southern. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use photolithograph to construct the arrays as taught by Chetverin. The artisan would have been motivated to do so based on the expressed suggestion of Chetverin.

7. Claims 157-158 and 167-168 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) and Chetverin et al (U.S. Patent No. 6,103,463, filed 19 February 1992) as applied to Claims 97 and 166 above and further in view of Kauvar (U.S. Patent No. 5,356,784, issued 18 October 1994) and/or Wang (U.S. Patent No. 4,618,475, issued 21 October 1986).

Regarding Claims 157-158 and 167-168, Southern teaches support comprising an array of four microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1). And Chetverin teaches a sectioned array for multiplex processing of the arrays individually without intermixing between the arrays (Column 10, lines 16-57). The reference further teaches the section arrays can be made by depressions on the array surface or by applying a lattice to the surface (e.g. Fig. 3, Column 10, lines 5-45) or by forming gel pads (Column 11, lines 1-22) which clearly suggests grooves and/or hydrophobic barriers but the reference is silent regarding a hydrophobic material for the lattice and/or “grooves”.

However, grooved and/or hydrophobic barriers were well known in the hybridization art at the time the invention was made as taught by Kauvar and Wang. Kauvar teaches an array of reaction regions on a solid support, each region having a plurality of ligands immobilized in the region wherein the regions are separated by a hydrophobic barriers (Column 7, lines 39-45) whereby reactions within the regions are defined thereby simplifying interpretation of assay results (Column 4, lines 37-58). Wang also teaches an array of reaction areas separated by hydrophobic barriers whereby cross-contamination is virtually eliminated and an "excellent appearance of the final product" is obtained (Column 4, lines 22-53).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Wang and/or Kauvar to the multiple arrays of Southern and/or Chetverin. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the expected benefit obtaining clearly defined assay results as is well known and routinely practiced in the art of bio-assays (Kauvar, Column 4, lines 37-58 and Wang, Column 4, lines 22-53).

8. Claims 162 and 172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) and Chetverin et al (U.S. Patent No. 6,103,463, filed 19 February 1992) as applied to Claims 97 and 166 above and further in view of Kauvar (U.S. Patent No. 5,356,784, issued 18 October 1994).

Regarding Claims 162 and 172, Southern teaches a 4 by 4 array but does not teach an 8 by 12 array. However, spotting probes in an 8 x 12 format (i.e. microtiter plate) was well known and routinely practiced in the art at the time the invention was made as taught by Kauvar who further teaches that any convenient or orderly pattern are chosen based on convenience (Column 4, lines 58-64).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Kauvar to the arrays of Southern based on desired format as taught by Kauvar (Column 4, lines 58-64).

Response to Arguments

9. Applicant asserts that the arrays of Chetverin are on a sheet onto which the arrays have been printed without physical barriers between each of the arrays on the sheet. Applicant further acknowledges that the pattern of wells have physical barriers but argues that each well does not constitute an array.

The arguments have been considered but are not found persuasive. Chetverin teaches numerous teachings of arrays separated by physical barriers as cited above.

Column 4, lines 6-30:

> A sectioned array as used herein is an array that is divided into sections, so that every individual area is **mechanically separated** from all other areas, such as, for example, a depression on the surface, or a "well". The areas have **different oligonucleotides immobilized** thereon. A **sectioned array allows many reactions to be performed simultaneously, both on the surface of the solid support and in solution, without mixing the products of different reactions**. The reactions occurring in different wells are highly specific, the specificity of the

reaction occurring in each well being determined by the nucleotide sequence of the oligonucleotide immobilized on the surface. This allows a large number of sortings and manipulations of nucleic acids to be carried out in parallel, by amplifying or modifying only those nucleic acids in each well that are perfectly hybridized to the immobilized oligonucleotides. Nucleic acids prepared on a sectioned array can be transferred to other arrays (replicated) by direct blotting of the wells' contents (printing), without mixing the contents of different wells of the same array. Furthermore, the presence of individual sections in arrays allows multiple re-hybridizations of bound nucleic acids to be performed, resulting in a significant increase in hybridization specificity. It is particularly advantageous according to this invention to use a binary array that is sectioned. (emphasis added)

Column 10, lines 6-67:

Sectioned arrays according to this invention can be used to increase the specificity of hybridization of nucleic acids to the immobilized oligonucleotides. After hybridization, unhybridized strands can be washed away. Hybridized strands can then be released into solution **without mixing materials present in different wells**. Released strands can be rebound to the oligonucleotides immobilized on the surface, and unhybridized strands can be washed away. Each successive release, rebinding, and washing increases the ratio of perfectly matched hybrids to mismatched hybrids.

The sectioned array can also be created by applying a lattice to the solid support and bonding it to the surface so that each area is surrounded by impermeable walls. The technique of application of the lattice to the support is not critical; such means are well known in the art and include using adhesives and heat bonding. The **areas of the array should be separated in a water tight manner**. An exploded perspective view of such a sectioned array is shown in FIG. 3. Support

or substrate 70, here a planar sheet, has mounted thereon and affixed thereto a lattice 72 comprised of a series of horizontal members 74, 76. The lattice members define a series of open areas which, in conjunction with support 70, define an array of wells 78. In some applications it is preferable to utilize a detachable lattice (or a removable cover sheet), so that the sectioned array can be converted back to a plain array. Oligonucleotides can be immobilized on the inner surface of the walls of the lattice, rather than on the bottoms of the wells. Irrespective of whether an array is sectioned permanently or temporarily, it is called herein a sectioned array. It is anticipated that the intermixing of the contents of an array can even be prevented by simply withdrawing materials by means of suction from each area as they are produced. A **sectioned array allows reactions to be performed simultaneously in individual areas**, both on the molecules attached to the surface of the array and on the molecules contained in the solution in each well. For some applications, it is particularly advantageous to use an array that is both sectioned and contains binary oligonucleotides, i.e., "sectioned binary arrays." (emphasis added)

Column 11, lines 11-22:

A replica array can initially be a flat sheet, and after the transfer **a lattice can be applied to the sheet, to produce a sectioned array**. To make the transfer more accurate, the buffer filling the original array can contain a low-gelling-temperature agarose. This buffer remains liquid at the higher temperatures that are required for strand amplification, but a gel forms when the array is chilled. In this case, a cover sheet plus a lattice can serve as a replica array. The cover sheet is first bonded to the lattice that forms the wells of the original array. After the agarose is converted to a gel by chilling, the original array is detached from the lattice and replaced by a new sheet. (emphasis added)

Additionally, Chetverin illustrates a survey array (42) printed from a partialing array area (31a) Fig. 7A/B. The survey array has multiple areas representing the multiple areas printed from the partialing array area. Therefore the partialing array comprise multiple arrays separated by a physical barrier provided by the walls of each well. It is maintained that Chetverin anticipates the invention as claimed.

Regarding the combination of Southern and Chetverin, Applicant argues that neither Southern not Chetverin teaches physical separation of the arrays and therefore cannot obviate the instantly claimed invention.

The argument has been considered but is not found persuasive. As discussed above Chetverin repeatedly teaches physical separation between arrays and further teaches the advantages of providing the physical separations (see citations above). It is maintained that the instantly claimed invention is obvious in view of the teaching of Southern and Chetverin.

Regarding the combination of Southern, Chetverin, Kauver and/or Wang, Applicant asserts that there is nothing in Wang that shows why a hydrophobic barrier would improve hybridization for Southern. Applicant further argues that Kauver's method of measuring mannose is irrelevant to the teaching of Southern and instantly claimed invention.

The arguments have been considered but are not found persuasive. As discussed above, both Southern and Chetverin teach multiple arrays and Chetverin teaches physical barriers between the arrays and the advantages provided by the barriers as discussed above. Kauver and Wang are merely cited to illustrate that

grooved and hydrophobic barriers were well-known and routinely used in bioassays. Thereby illustrating that grooved and hydrophobic barriers are functionally equivalent to the physical barriers of Chetverin. It would have been obvious to the ordinary artisan to use any functionally equivalent barrier in the arrays of Southern and/or Chetverin based on availability of materials and/or hydrophobic/hydrophilic properties of the desired assays. The courts have stated that it would be obvious to one of skill in the art in view of the method to "substitute one equivalent for another" and "express suggestion to substitute one equivalent for another need not be present to render such substitution obvious" (see *In re Fout*, 213 USPQ 532).

Conclusion

10. No claim is allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Betty Forman whose telephone number is (571)272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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